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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/786,725	04/23/2001	Hans-Werner Heinrich	101195-44	4120

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EXAMINER	
WILLIAMS, KAREN M	
ART UNIT	PAPER NUMBER
PCT	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/19/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	09/786,725	HEINRICH ET AL.	
	Examiner	Art Unit	
	James L. Grun	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 January 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-15 and 17-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-15 and 17-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

The amendment filed 12 January 2007 is acknowledged and has been entered. Claims 19 and 20 are newly added. Claims 2 and 16 have been cancelled. Claims 1, 3-15, and 17-20 remain in the case.

The disclosure is objected to because of the following informalities: the specification contains too many grammatical, idiomatic, and spelling errors to list specifically and should be carefully revised. Appropriate correction is required.

Applicant's arguments filed 12 January 2007 have been fully considered but they are not deemed to be persuasive. Applicant urges that although inconsistencies in grammar may exist, the text is understandable. This is not found persuasive because of the number of errors.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to under 35 U.S.C. § 112, first paragraph, as failing to provide an adequate written description of the invention, and failing to adequately teach how to make and/or use the invention, i.e. failing to provide an enabling disclosure.

Claims 1, 3-11 and 17-20 are rejected under 35 U.S.C. 112, first paragraph, for reasons of record, that the specification contains subject matter which was not described in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, and which was not described in

such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Applicant's arguments filed 12 January 2007 have been fully considered but they are not deemed to be persuasive.

Applicant urges that elastase assay reagents and steps were known to the art.

As set forth previously, applicant teaches only polyclonal antibodies and provides no description or guidance to any monospecific species which functions in the invention. As set forth, adequate written description requires more than a mere statement that a product is part of the invention, more than a reference to a potential method of isolating it, and more than a generic statement which defines a genus of products by only their functional activity. As set forth, the product itself is required as well as recitation of a representative number of products falling within the scope of a claimed genus. Moreover, as set forth, all possible analogs of a product are not enabled by a disclosure wherein the characteristics of the analogs are unpredictable.

The argument is also not found persuasive because, as set forth, "there is a failure to meet the enablement requirements that cannot be rectified by asserting that all the disclosure related to the process is within the skill of the art", "[i]t is the specification, not the knowledge of one skilled in the art, that must supply the novel aspects of an invention in order to constitute adequate enablement." As set forth, absent further written description and guidance from applicant, one would have no assurance of successfully obtaining appropriate functional reagents and predictably performing the method as suggested by applicant. As set forth, there is nothing in the specification to indicate which, if any, of the anti-peptide antibodies bind to all isoforms so that one could practice the invention as desired and claimed to detect all isoforms with a single

antibody absent further unguided unpredictable experimentation to complete applicant's suggested invention. Applicant also provides no guidance for usable combinations, particularly since some of the peptides suggested for use by applicant would be expected to elicit antibodies that bind to an isoform that corresponds to porcine elastase, which is not expressed in the human pancreas, and which would complicate the assay in certain patient populations. Further, in the reasons of record, applicant does not teach combinations usable together. Moreover, one could not predict the ability of any of the antibodies to the suggested peptides to bind to non-denatured protein as found in a fluid sample from a patient for the reasons of record.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 3-15, and 17-20 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 3-5, and 20 involve method claims and, as such, they should clearly set forth the various method steps in a positive, sequential manner using active tense verbs such as mixing, reacting, and detecting. "Employing" or "using" are not valid method steps. In these claims, "the antigen" lacks antecedent basis.

In claims 3-4, improper Markush language is used to claim the members of the group. The alternatives "selected from...or" or "selected from the group consisting of...and" are acceptable.

In claim 6, "the pancreas" lacks antecedent basis. It is not clear what applicant intends as excluded because the excluded amino acid sequence is of a peptide not an iso-enzyme.

In claim 7 and claims dependent thereupon, incorrect "SEQ ID NO:" identifiers are recited. It is not clear what is intended as encompassed by "such" peptides or antibodies, i.e. are the elements merely exemplary of what is within the metes and bounds of the desired invention or is the invention limited to only those elements specifically recited.

In claim 8, it is not clear how one determines what is "suitable" and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Claims 10 and 11 are of improper dependent form for failing to further limit the subject matter of a previous claim.

Claims 12-15 each fails to end with a period.

Claims 17 and 18 are indefinite in that the claims fail to further limit the subject matter of a previous claim and set forth an intended use but fail to point out what components are included or excluded by the claim language. In these claims, "the diagnosis" lacks antecedent basis.

In claim 19, it is not clear what step of claim 7, if any, is being further limited, e.g. it is not clear if coupling is the only step being performed or if coupling involves any of the recited peptides. Perhaps applicant intended the subject matter of the claim to depend from claim 8.

In claim 20, it is not clear what step of claim 3, if any, is being further limited because "the induction of B-cells" lacks antecedent basis. It is not clear what is intended by "hybridoma cells which are cultivated in cell lines."

Applicant's arguments filed 12 January 2007 have been fully considered but they are not deemed to be persuasive. Notwithstanding applicant's assertions to the contrary, applicant's

amendments have not obviated rejections under this statute for the reasons set forth above. Notwithstanding applicant's assertions to the contrary, product claims do not further limit method claims.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3-8, 10-15, and 17-20 are rejected under 35 U.S.C. § 102(b) as being anticipated by Scheefers et al. (U.S. Pat. No. 5,622,837) in light of the instant disclosure for reasons of record.

Claims 1, 3-8, 10, 12-15, 17 and 18 are rejected under 35 U.S.C. § 102(b) as being anticipated by Sziegoleit et al. (Clin. Biochem. 22: 79, 1989) in light of the instant disclosure for reasons of record.

The examiner would note that the disclosures of the references are considered as a whole and are not limited to only the monoclonal antibody commercial embodiment of the sandwich assay derived from Scheefers et al. As set forth, Sziegoleit et al. teach elicitation of polyclonal antibodies to purified enzyme and Scheefers et al. teach elicitation of both polyclonal and monoclonal antibodies to purified enzyme and fragments thereof, for use in sandwich enzyme-linked immunosorbent assay for diagnosis of pancreatic diseases. As set forth, the enzyme preparation would inherently be a mixture of the elastase I isoforms (i.e. elastases IIIA and IIIB),

and polyclonal antibodies elicited thereto would inherently bind to the isoforms and cross-react with similar epitopes as found in elastase II. As set forth, the Patent and Trademark Office does not have the facilities and resources to provide the *factual* evidence needed in order to establish that there is a difference, in the first place, between the reagents of the prior art and those instantly disclosed and, that if there is such a difference, that such a difference would have been considered unexpected, i.e. unobvious, by one of ordinary skill in the art. The burden is upon applicant to present such factual evidence. See e.g. In re Best (195 USPQ 430 (CCPA 1977)) or Ex parte Phillips (28 USPQ2d 1302 (BPAI 1993)).

Applicant's arguments filed 12 January 2007 have been fully considered but they are not deemed to be persuasive.

Applicant proffers a synopsis of publications, some comparing the sensitivity and specificity of a single commercial assay based on the disclosures of the cited publications, particularly that of Scheefers et al., and unspecified embodiments of the instant disclosure, as evidence of the "practicability and suitability of the [instant] invention and the distinction over the prior art...". These are not found persuasive for a number of reasons. Applicant's arguments are again focused on a single commercial embodiment based on the monoclonal antibodies taught in Scheefers et al. and are not drawn to the teachings of each of the applied references as a whole; particularly those involving the use of polyclonal antibodies elicited to purified whole enzyme. The arguments are, thus, not found persuasive because the teachings of the references are not limited to the single embodiment. However, the examiner would note that many of the abstracts listed by applicant teach the comparability of the two tested assays. Moreover, the arguments are also not found persuasive because any showing of a slight difference in specificity

between two single embodiments, as in at least one of the abstracts, is not a showing commensurate in scope with the invention as instantly claimed, or the assays as taught in the prior art, and does not rise to the level of *factual* evidence of a patentable difference between the reagents of the prior art and those instantly disclosed. Indeed, it is not even clear what embodiment of applicant's suggested invention was tested against the assay using the particular monoclonal antibodies taught in Scheefers et al. Notwithstanding applicant's implications to the contrary, a showing of a difference in degree is not evidence of a difference in kind.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR § 1.136(a).

A SHORTENED STATUTORY PERIOD FOR REPLY TO THIS FINAL ACTION IS SET TO EXPIRE **THREE MONTHS** FROM THE MAILING DATE OF THIS ACTION. IN THE EVENT A FIRST REPLY IS FILED WITHIN **TWO MONTHS** OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE **THREE-MONTH** SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR REPLY EXPIRE LATER THAN **SIX MONTHS** FROM THE MAILING DATE OF THIS FINAL ACTION.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James L. Grun, Ph.D., whose telephone number is (571) 272-0821. The examiner can normally be reached on weekdays from 9 a.m. to 5 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, SPE, can be contacted at (571) 272-0823.

The phone number for official facsimile transmitted communications to TC 1600, Group 1640, is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application, or requests to supply missing elements from Office communications, should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

James L. Grun, Ph.D.
April 11, 2007

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